

PATENT
ATTORNEY DOCKET: 54719.000011

8
DmT
72502

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Application of:)

Randal J. KIRK et al.)

Application Number: 09/986,426)

Filed: November 8, 2001)

For: USE OF PROTEIN CONFORMATION FOR THE PROTECTION AND RELEASE
OF CHEMICAL COMPOUNDS)

Group Art Unit: 1651

Examiner: To Be Assigned

RECEIVED
JUL 24 2002
TECH CENTER 1600/2900

INFORMATION DISCLOSURE STATEMENT

Director U.S. Patent and Trademark Office
Washington, D.C. 20231

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, and in compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, applicants are submitting herewith copies of the references listed on the attached Form PTO/SB/08A for consideration and to be made of record herein by the U.S. Patent and Trademark Office in the above-captioned application.

Consideration of the foregoing plus the prompt return of a copy of the enclosed Form PTO/SB/08A with the Examiner's initials in the left column in accordance with MPEP 609 are respectfully requested.

Applicants' submission of the Information Disclosure Statement shall not be construed as an admission that the cited references are prior art to the present invention, or that the cited references qualify as printed publications. The submission of this IDS also shall not be construed as a representation that a prior art search has been performed.

In accordance with 37 C.F.R. § 1.97(b), this Information Disclosure Statement is believed to be submitted prior to issuance of a first Office Action and within three months of the filing date of the application. Therefore, it is respectfully submitted that no fee is required for

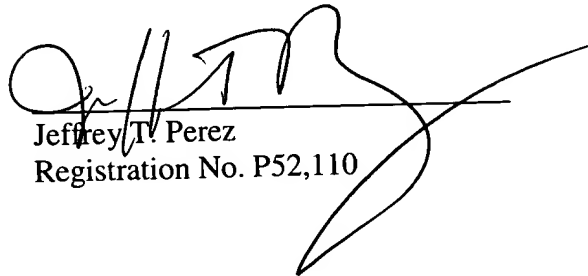
consideration of this information. However, in the event any fee is deemed necessary, the Commissioner is authorized to charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS

July 23, 2002

By:

A handwritten signature in black ink, appearing to read 'Jeffrey T. Perez', is written over a horizontal line. The signature is stylized with a large, sweeping loop at the end.

Jeffrey T. Perez

Registration No. P52,110

HUNTON & WILLIAMS
1900 K Street, N.W.
Washington, D.C. 20006
Telephone (202) 955-1500
Fax: (202) 778-2201

Please type a plus sign (+) inside this box



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 4

Complete if Known

Application Number 09/986,426
Filing Date November 8, 2001
First Named Inventor Randal J. KIRK, et al
Group Art Unit 1651
Examiner Name To Be Assigned
Attorney Docket Number 54719.000011

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	U1	3,846,399		Hirschmann et al.	11/05/74	
	U2	4,040,907		Ullman et al.	08/09/77	
	U3	4,356,166		Peterson et al.	10/26/82	
	U4	4,399,121		Albarella et al.	08/16/83	
	U5	4,552,864		Antoni et al.	11/12/85	
	U6	4,863,735		Kohn et al.	09/05/89	
	U7	4,976,962		Bichon et al.	12/11/90	
	U8	5,087,616		Myers et al.	02/11/92	
	U9	5,238,714		Wallace et al.	08/24/93	
	U10	5,534,496		Lee et al.	07/09/96	
	U11	5,762,909		Uzgiris	06/09/98	
	U12	5,767,227		Latham et al.	06/16/98	
	U13	5,846,743		Janmey et al.	12/08/98	
	U14	5,851,536		Yager et al.	12/22/98	
	U15	5,882,645		Toth et al.	03/16/99	
	U16	5,910,569		Latham et al.	06/08/99	
	U17	5,948,750		Garsky et al.	09/07/99	
	U18	5,952,294		Lazo et al.	09/14/99	
	U19	5,977,163		Li et al.	11/02/99	
	U20	6,030,941		Summerton et al.	02/29/00	
	U21	6,306,993	B1	Rothbard et al.	10/23/01	
	U22	5,073,641		Bundgaard et al.	12/17/91	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ₆
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	F1	WO	97/36616		Seymour et al.	10/09/97		

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box

+

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 4

Complete if Known

Application Number	09/986,426
Filing Date	November 8, 2001
First Named Inventor	Randal J. KIRK et al.
Group Art Unit	1651
Examiner Name	To Be Assigned
Attorney Docket Number	54719.000011

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	P1	ORTEN, James M. et al., "Thyroxine," <i>Human Biochemistry</i> , 9 th Ed., C.V. Mosby Company, St. Louis, pp. 401-405 (1975).	
	P2	LI, Chun, et al., "Complete Regression of Well-Established Tumors Using a Novel Water-Soluble Poly(L-Glutamic Acid)-Paclitaxel Conjugate," <i>Cancer Res</i> , 58:2404-2409 (1998).	
	P3	KRAMER, Werner et al., "Intestinal Absorption of Peptides by Coupling to Bile Acids," <i>The Journal of Biochemistry</i> , 269(14):10621-10627 (1994).	
	P4	RAWITCH, Allen B., et al., "The Isolation of Identical Thyroxine Containing Amino Acid Sequences from Bovine, Ovine and Porcine Thyroglobulins," <i>Biochemical and Biophysical Research Communications</i> , 118(2):423-429 (1984).	
	P5	MARRIQ, Claudine, et al., "Amino Acid Sequence of the Unique 3,5,3'-Triiodothyronine-Containing Sequence from Porcine Thyroglobulin," <i>Biochemical and Biophysical Research Communications</i> , 112(1):206-213 (1983).	
	P6	SAWADA, Kyoko, et al., "Recognition of L-Amino Acid Ester Compounds by Rat Peptide Transporters PEPT1 and PEPT2," <i>Journal of Pharmacology and Experimental Therapeutics</i> , 291(2):705-709 (1999).	
	P7	DE VRUEH, Remco L.A., et al., "Transport of L-Valine-Acyclovir Via the Oligopeptide Transporter in the Human Intestinal Cell Line, Caco-2," <i>Journal of Pharmacology and Experimental Therapeutics</i> , 286(2):1166-1170 (1988).	
	P8	GUO, Ailan, et al., "Interactions of a Nonpeptidic Drug, Valacyclovir, with the Human Intestinal Peptide Transporter (hPEPT1) Expressed in a Mammalian Cell Line," <i>Journal of Pharmacology and Experimental Therapeutics</i> , 289(1):448-454 (1999).	
	P9	BURNETTE, Thimysta C., et al., "Metabolic Disposition of the Acyclovir Prodrug Valaciclovir in the Rat," <i>Drug Metabolism and Disposition</i> , 22(1):60-64 (1994).	
	P10	AGGARWAL, et al., "Synthesis and Biological Evaluation of Prodrugs of Zidovudine," <i>J. Med. Chem.</i> , 33(5):1505-1511 (1990).	
	P11	ZUNINO, Franco, et al., "Comparison of Antitumor Effects of Daunorubicin Covalently Linked to Poly-L-Amino Acid Carriers," <i>European Journal of Cancer & Clinical Oncology</i> , 20(3):121-125 (1984).	
	P12	HAVRANOVA, Marie et al., "A High-Molecular Mass Derivative of Trypsin-Kallikrein Inhibitor for Potential Medical Use, II," <i>Hoppe-Seyler's Z. Physiol. Chem.</i> , 363:295-303 (1982).	
	P13	RYSER, Hugues J.P., et al., "Conjugation of Methotrexate to Poly (L-lysine) Increases Drug Transport and Overcomes Drug Resistance in Cultured Cells," <i>Proc. Natl. Acad. Sci. USA</i> , 75(8):3867-3870 (1978).	
	P14	HAN, Hyo-Kyung, et al., "Targeted Prodrug Design to Optimize Drug Delivery," <i>AAPS PharmSci</i> , 2(1): Article 6 (2000).	
	P15	TAMAI, I., et al., "Improvement of L-dopa Absorption by Dipeptidyl Derivation, Utilizing Peptide Transporter PepT1," <i>J. Pharma. Sci.</i> , 87(12):1542-1546 (1988), Abstract.	

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

RECEIVED
JUL 21 2002
TECH CENTER 1600/2900

O I P E
JUL 23 2002
PATENT & TRADEMARK OFFICE

Please type a plus sign (+) inside this box

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

Complete if Known

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet **3** of **4**

Application Number **09/986,426**
Filing Date **November 8, 2001**
First Named Inventor **Randal J. KIRK, et al.**
Group Art Unit **1651**
Examiner Name **To Be Assigned**
Attorney Docket Number **54719.000011**

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	P16	OH, D.M., et al., "Drug Transport and Targeting. Intestinal Transport," <i>Pharma Biotechnol.</i> , 12:59-88 (1999), Abstract.	
	P17	BALIMANE, P., et al., "Effect of Ionization on the Variable Uptake of Valacyclovir via the Human Intestinal Peptide Transporter (hPepT1) in CHP cells," <i>Biopharm Drug Dispos.</i> , 21(5):165-174 (2000), Abstract.	
	P18	KNUTTER, I, et al., "A Novel Inhibitor of the Mammalian Peptide Transporter PEPT1," <i>Biochemistry</i> , 40(14):4454-4458 (2001), Abstract.	
	P19	SHEN, H., et al., "Developmental Expression of PEPT1 and PEPT2 in Rat Small Intestine, Colon, and Kidney," <i>Pediatr Res</i> , 49(6):789-795 (2001), Abstract	
	P20	FRIEDRICHSEN, G.M., et al., "Model Prodrugs Designed for the Intestinal Peptide Transporter. A Synthetic Approach for Coupling of Hydroxy-Containing Compounds to Dipeptides," <i>Eur J Pharm Sci</i> , 14(1):13-19 (2001, Abstract.	
	P21	HAN H., et al., "5'-Amino Acid Esters of Antiviral Nucleosides, Acyclovir, and AZT and Absorbed by the Intestinal PEPT1 Peptide Transporter," <i>Pharm Res</i> , 15(8):1154-1159 (1998), Abstract.	
	P22	BLIMANE, P.V., et al., "Direct Evidence for Peptide Transporter (PepT1)-Mediated Uptake of a Nonpeptide Prodrug, Valacyclovir," <i>Biochem Biophys Res Commun</i> , 250(2):246-251 (1998), Abstract.	
	P23	HAN, H.K., et al., "Cellular Uptake Mechanism of Amino Acid Ester prodrugs in Caco-2hPEPT1 Cells Overexpressing a Human Peptide Transporter," <i>Pharm Res</i> , 15(9):1382-1386 (1998), Abstract.	
	P24	SHIRAGA, T., et al., "Cellular and Molecular Mechanisms of Dietary Regulation on Rat Intestinal H+/Peptide Transporter PepT1," <i>Gastroenterology</i> , 116(2):354-362 (1999), Abstract.	
	P25	GUO, A., et al., "Interactions of a Nonpeptidic Drug, Valacyclovir, with the Human Intestinal Peptide Transporter (hPEPT1) Expressed in a Mammalian Cell Line," <i>Pharmacol Exp Ther</i> , 289(1):448-454 (1999), Abstract.	
	P26	AMIDON, G.L., et al., "5'-Amino Acid Esters of Antiviral Nucleosides, Acyclovir, and AZT are Absorbed by the Intestinal PEPT1 Peptide Transporter," <i>Pharm Res</i> , 16(2):175 (1999), Abstract.	
	P27	LEIBACH, F.H, et al., "Peptide Transporters in the Intestine and the Kidney," <i>Annu Rev Nutri</i> , 16:99-119 (1996), Abstract.	
	P28	HERRERA-RUIZ, D., et al., "Spatial Expression Patterns of Peptide Transporters in the Human and Rat Gastrointestinal Tracts, Caco-2 in vitro Cell Culture Model, and Multiple Human Tissues," <i>AAPS PharmSci</i> , 3(1):E9 (2001), Abstract.	
	P29	TOTH, Istvan, "A Novel Chemical Approach to Drug Delivery: Lipidic Amino Acid Conjugates," <i>Journal of Drug Targeting</i> , 2:217-239 (1994).	
	P30	NEGISHI, Naoki, et al., "Coupling of Naltrexone to Biodegradable Poly (α -Amino Acids)," <i>Pharmaceutical Research</i> , 4(4):305-310 (1987).	

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.